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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/596,444	06/19/2000	Wei Huang	LJL 354B	4000

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EXAMINER
GABEL, GAILENE

ART UNIT	PAPER NUMBER
1641	16

DATE MAILED: 09/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/596,444	HUANG ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-46* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-17, drawn to method of detecting phosphate group activity on a substrate using luminescence polarization measurement of a luminescent peptide, wherein the peptide has

- SEQ ID No. 8, classified in class 435, subclass 7.72, for example.
- SEQ ID No. 9, classified in class 435, subclass 7.72.
- SEQ ID No. 10, classified in class 435, subclass 7.72.
- SEQ ID No. 11, classified in class 435, subclass 7.72.
- SEQ ID No. 12, classified in class 435, subclass 7.72.
- SEQ ID No. 13, classified in class 435, subclass 7.72.
- SEQ ID No. 14, classified in class 435, subclass 7.72.
- SEQ ID No. 15, classified in class 435, subclass 7.72.
- SEQ ID No. 16, classified in class 435, subclass 7.72.
- SEQ ID No. 17, classified in class 435, subclass 7.72.
- SEQ ID No. 18, classified in class 435, subclass 7.72.
- SEQ ID No. 19, classified in class 435, subclass 7.72.
- SEQ ID No. 20, classified in class 435, subclass 7.72.
- SEQ ID No. 29, classified in class 435, subclass 7.72.
- SEQ ID No. 30, classified in class ***, subclass ***.

II. Claims 18-29, drawn to method of detecting phosphate group activity on a substrate using fluorescence resonance energy transfer measurements, classified in class 436, subclass 172, for example.

III. Claims 30-33, drawn to substrate composition which is a peptide having

- SEQ ID No. 31, classified in class 514, subclass 2, for example.
- SEQ ID No. 32, classified in class 514, subclass 2.
- SEQ ID No. 33, classified in class 514, subclass 2.
- SEQ ID No. 34, classified in class 514, subclass 2.
- SEQ ID No. 35, classified in class 514, subclass 2.
- SEQ ID No. 36, classified in class 514, subclass 2.
- SEQ ID No. 37, classified in class 514, subclass 2.
- SEQ ID No. 38, classified in class 514, subclass 2.
- SEQ ID No. 39, classified in class 514, subclass 2.
- SEQ ID No. 40, classified in class 514, subclass 2.
- SEQ ID No. 41, classified in class 514, subclass 2.
- SEQ ID No. 42, classified in class 514, subclass 2.
- SEQ ID No. 43, classified in class 514, subclass 2.
- SEQ ID No. 44, classified in class 514, subclass 2.
- SEQ ID No. 45, classified in class 514, subclass 2.
- SEQ ID No. 46, classified in class 514, subclass 2.

- SEQ ID No. 47, classified in class 514, subclass 2.

- SEQ ID No. 48, classified in class 514, subclass 2.

IV. Claims 34-35, drawn to peptide composition, comprising

- a peptide having SEQ ID No. 8, classified in class 435, subclass 24, for example.

- a peptide having SEQ ID No. 9, classified in class 435, subclass 24.

- a peptide having SEQ ID No. 10, classified in class 435, subclass 24.

- a peptide having SEQ ID No. 11, classified in class 435, subclass 24.

- a peptide having SEQ ID No. 12, classified in class 435, subclass 24.

- a peptide having SEQ ID No. 13, classified in class 435, subclass 24.

- a peptide having SEQ ID No. 14, classified in class 435, subclass 24.

- a peptide having SEQ ID No. 15, classified in class 435, subclass 24.

- a peptide having SEQ ID No. 16, classified in class 435, subclass 24.

- a peptide having SEQ ID No. 17, classified in class 435, subclass 24.

- a peptide having SEQ ID No. 18, classified in class 435, subclass 24.

- a peptide having SEQ ID No. 19, classified in class 435, subclass 24.

- a peptide having SEQ ID No. 20, classified in class 435, subclass 24.

- a peptide having SEQ ID No. 29, classified in class 435, subclass 24.

- a peptide having SEQ ID No. 30, classified in class 435, subclass 24.

V. Claims 36-39, drawn to composition that binds peptide, wherein the peptide has

- SEQ ID No. 8, classified in class 436, subclass 548, for example.
- SEQ ID No. 9, classified in class 436, subclass 548.
- SEQ ID No. 10, classified in class 436, subclass 548.
- SEQ ID No. 11, classified in class 436, subclass 548.
- SEQ ID No. 12, classified in class 436, subclass 548.
- SEQ ID No. 13, classified in class 436, subclass 548.
- SEQ ID No. 14, classified in class 436, subclass 548.
- SEQ ID No. 15, classified in class 436, subclass 548.
- SEQ ID No. 16, classified in class 436, subclass 548.
- SEQ ID No. 17, classified in class 436, subclass 548.
- SEQ ID No. 18, classified in class 436, subclass 548.
- SEQ ID No. 19, classified in class 436, subclass 548.
- SEQ ID No. 20, classified in class 436, subclass 548.
- SEQ ID No. 29, classified in class 436, subclass 548.
- SEQ ID No. 30, classified in class 436, subclass 548.

VI. Claims 40-41, drawn to compound of the formula having

- SEQ ID No. 21, classified in class 435, subclass 183, for example.
- SEQ ID No. 22, classified in class 435, subclass 183.
- SEQ ID No. 23, classified in class 435, subclass 183.

VII. Claims 42 and 44-46, drawn to method of determining tyrosine kinase activity, classified in class 436, subclass 517, for example.

VIII. Claim 43, drawn to method of detecting a compound having kinase modulating activity, classified in class 424, subclass 9.2, for example.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and all of Inventions II-III,VI-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects in that Invention 1 uses luminescence polarization measurements of a luminescent compound to detect phosphate group activity on a substrate, Invention II uses fluorescence resonance energy transfer measurements to detect phosphate group activity on a substrate, Invention III is a kinase substrate, Invention VI is a compound, Invention VII determines kinase activity by measuring polarization on a compound which correlates with kinase activity, and Invention VIII determines polarization to assess modulation of a compound for kinase activity.

Further, each of inventions I, III, and VI are drawn to a plurality of patentably distinct inventions by virtue of the peptides having materially different amino acid

sequences as evidenced by distinct SEQ ID Numbers. These separate peptides bear distinct structural or biochemical properties as substantiated by the separate SEQ ID numbers having different binding epitopes for unique diverse antibodies. **Therefore, each disclosed patentably distinct peptide is considered a separate invention.**

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the peptide of Invention IV can be used in collision-induced dissociation studies of peptide fragments.

Further, each of inventions I and IV are drawn to a plurality of patentably distinct inventions by virtue of the peptides having materially different amino acid sequences as evidenced by distinct SEQ ID Numbers. These separate peptides bear distinct structural or biochemical properties as substantiated by the separate SEQ ID numbers having different binding epitopes for unique diverse antibodies. **Therefore, each disclosed patentably distinct peptide is considered a separate invention.**

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the binding partner of

Invention V can be used in equilibrium titration studies for protein binding kinetic studies.

Further, each of inventions I and V are drawn to a plurality of patentably distinct inventions by virtue of the peptides having materially different amino acid sequences as evidenced by distinct SEQ ID Numbers. These separate peptides bear distinct structural or biochemical properties as substantiated by the separate SEQ ID numbers having different binding epitopes for unique diverse antibodies. **Therefore, each disclosed patentably distinct peptide is considered a separate invention.**

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the substrate of Invention III can be incorporated onto a derivatized bead for flow cytometric measurements.

Further, invention III is drawn to a plurality of patentably distinct inventions by virtue of the peptides having materially different amino acid sequences as evidenced by distinct SEQ ID Numbers. These separate peptides bear distinct structural or biochemical properties as substantiated by the separate SEQ ID numbers having different binding epitopes for unique diverse antibodies. **Therefore, each disclosed patentably distinct peptide is considered a separate invention.**

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the peptide of Invention IV can be used in collision-induced dissociation studies of peptide fragments.

Further, invention IV is drawn to a plurality of patentably distinct inventions by virtue of the peptides having materially different amino acid sequences as evidenced by distinct SEQ ID Numbers. These separate peptides bear distinct structural or biochemical properties as substantiated by the separate SEQ ID numbers having different binding epitopes for unique diverse antibodies. **Therefore, each disclosed patentably distinct peptide is considered a separate invention.**

Inventions II and V is related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the binding partner of Invention V can be used in equilibrium titration studies for protein binding kinetic studies.

Further, invention V is drawn to a plurality of patentably distinct inventions by virtue of the peptides having materially different amino acid sequences as evidenced by distinct SEQ ID Numbers. These separate peptides bear distinct structural or

biochemical properties as substantiated by the separate SEQ ID numbers having different binding epitopes for unique diverse antibodies. **Therefore, each disclosed patentably distinct peptide is considered a separate invention.**

Inventions II and all of Inventions VI-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects in that Invention II uses fluorescence resonance energy transfer measurements to detect phosphate group activity on a substrate, Invention VI is a compound, Invention VII determines kinase activity by measuring polarization on a compound which correlates with kinase activity, and Invention VIII determines polarization to assess modulation of a compound for kinase activity.

Further, invention VI is drawn to a plurality of patentably distinct inventions by virtue of the peptides having materially different amino acid sequences as evidenced by distinct SEQ ID Numbers. These separate peptides bear distinct structural or biochemical properties as substantiated by the separate SEQ ID numbers having different binding epitopes for unique diverse antibodies. **Therefore, each disclosed patentably distinct peptide is considered a separate invention.**

Inventions III and all of Inventions IV-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects in that Invention III is a kinase substrate composition, Invention IV is a luminescent peptide composition, Invention V is a composition that binds a peptide having an enzyme, Invention VI is a compound formula.

Further, each of inventions III, IV, V, and VI are drawn to a plurality of patentably distinct inventions by virtue of the peptides having materially different amino acid sequences as evidenced by distinct SEQ ID Numbers. These separate peptides bear distinct structural or biochemical properties as substantiated by the separate SEQ ID numbers having different binding epitopes for unique diverse antibodies. **Therefore, each disclosed patentably distinct peptide is considered a separate invention.**

Inventions III and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the substrate of Invention III can be incorporated onto a derivatized bead for flow cytometric measurements.

Further, invention III is drawn to a plurality of patentably distinct inventions by virtue of the peptides having materially different amino acid sequences as evidenced by distinct SEQ ID Numbers. These separate peptides bear distinct structural or

biochemical properties as substantiated by the separate SEQ ID numbers having different binding epitopes for unique diverse antibodies. **Therefore, each disclosed patentably distinct peptide is considered a separate invention.**

Inventions III and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the substrate of Invention III can be incorporated into nanocrystals comprising metal for measurement of specific binding kinetics.

Further, invention III is drawn to a plurality of patentably distinct inventions by virtue of the peptides having materially different amino acid sequences as evidenced by distinct SEQ ID Numbers. These separate peptides bear distinct structural or biochemical properties as substantiated by the separate SEQ ID numbers having different binding epitopes for unique diverse antibodies. **Therefore, each disclosed patentably distinct peptide is considered a separate invention.**

Inventions IV, V, VI, VII, and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects in the Invention IV is a luminescent peptide,

Invention V is a composition that binds a peptide having an enzyme, Invention VI is a compound, Invention VII determines kinase activity by measuring polarization on a compound which correlates with kinase activity, and Invention VIII determines polarization to assess modulation of a compound for kinase activity.

Further, each of inventions IV-VI are drawn to a plurality of patentably distinct inventions by virtue of the peptides having materially different amino acid sequences as evidenced by distinct SEQ ID Numbers. These separate peptides bear distinct structural or biochemical properties as substantiated by the separate SEQ ID numbers having different binding epitopes for unique diverse antibodies. **Therefore, each disclosed patentably distinct peptide is considered a separate invention.**

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because the search required for each of the Groups is not required for each of the other Groups, restriction for examination purposes as indicated is proper. Literature search for each of the methods and compositions is distinct since the structural requirements of each invention are different. While searches would be expected to overlap, there is no reason to expect the searches to be coextensive.

Groups I, III, IV, V, and VI are also drawn to a plurality of disclosed patentably distinct inventions comprising materially different and patentably distinct peptides. Should a Group be elected, Applicant is also required to elect a single amino acid

sequence defining a patentably distinct peptide, even though this requirement is traversed. The separate proteins and/or peptides bear no structural or biochemical property in common and therefore each particular peptide claimed would require a separate area of search.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Should applicant traverse on the grounds that the different amino acid sequences are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the peptides having separated amino acid sequences to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday to Thursday, 6:30 AM - 4:00 PM and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 308-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641

Gailene R. Gabel
September 17, 2002